

## II. REMARKS

### **Formal Matters**

Claims 10-13 and 28-30 are pending after entry of the amendments set forth herein.

Claims 10-13 and 28-30 were examined and were rejected. Claims 14-24 were withdrawn from consideration.

Claims 14-24 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### **Rejection under 35 U.S.C. §112, first paragraph**

Claims 10-13 and 28-30 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

The final Office Action stated that neither the specification nor the art has established that antibody binding to the polyglutamine expansion region of the huntingtin protein occurs in the same region that binds the unknown and undisclosed cellular receptor. The final Office Action stated that measuring the interaction between the polyglutamine expansion protein and the antibody “will not provide any insight between the interaction of the polyglutamine protein binding to its unknown and undisclosed putative cellular receptor.” Final Office Action, page 5. The final Office Action stated that there is no correlation in the prior art or in the instant specification which would indicate that a compound that interferes with the antibody binding to the polyglutamine expansion of the huntingtin protein would interfere with the binding of the polyglutamine expansion-containing protein to the normal cellular target. Applicants respectfully traverse the rejection.

*The instant specification provides an enabling disclosure.*

The specification states that agents identified by the claimed method inhibit the binding interaction between the polyglutamine expansion-containing protein and a cellular target of the protein. Specification, page 11, lines 24-29. The specification describes in ample detail how to determine whether a given agent modulates binding between a polyglutamine expansion-containing protein and an

antibody. Those skilled in the art could readily determine whether such an agent also modulates binding between the polyglutamine expansion-containing protein and its cellular target. Accordingly, those skilled in the art could use the invention as claimed.

*The Office has not presented sufficient reasons to doubt that the claimed method is enabled.*

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

The Office has presented no convincing reasons why a person skilled in the art would doubt that an agent that modulates a binding interaction between a polyglutamine expansion-containing protein and its cellular target can be identified using the claimed method.

The final Office Action asserted that measuring the interaction between the polyglutamine expansion protein and the antibody "will not provide any insight between the interaction of the polyglutamine protein binding to its unknown and undisclosed putative cellular receptor." Final Office Action, page 5. As provided for under 37 C.F.R. §1.104(d)(2), the Office is invited to submit an affidavit providing scientific evidence and reasoning for the assertion.

*Those skilled in the art would find it reasonable to use the claimed assay to identify agents that inhibit binding of a protein containing a polyglutamine expansion to its cellular target.*

Those skilled in the art would find it reasonable to expect that an agent that modulates binding interaction between an antibody and a polyglutamine expansion of a polyglutamine expansion-

containing protein would also modulate a binding interaction between a polyglutamine expansion-containing protein and a cellular target of the protein. Antibodies are proteins, and the cellular target of the polyglutamine expansion-containing protein is expected to be a protein. The antibody binding pocket is expected to be a mimic for a cellular target of a polyglutamine expansion-containing protein. In view of such, those skilled in the art would expect that the binding interaction between an antibody to a polyglutamine expansion of a polyglutamine expansion-containing protein would serve as a surrogate for the binding interaction between a polyglutamine expansion-containing protein and a cellular target of the protein.

The fact that those skilled in the art would find it reasonable to use the claimed assay to identify agents that inhibit binding of a protein containing a polyglutamine expansion to its cellular target is supported by the Declaration of Ross Stein, provided herewith as Exhibit 1. As such, those skilled in the art would find it reasonable to use the claimed assay to identify agents that inhibit binding of a protein containing a polyglutamine expansion to its cellular target.

*Conclusion as to the rejection under 35 U.S.C. §112, first paragraph*

Applicants submit that the rejection of claims 10-13 and 28-30 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

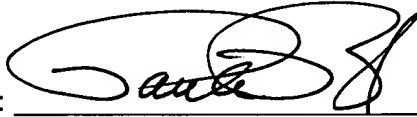
### III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL161DIV.

Respectfully submitted,  
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Date: July 16, 2004

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